10A NCAC 13P .0901 is proposed for amendment as follows:

10A NCAC 13P .0901 LEVEL I TRAUMA CENTER CRITERIA

To receive designation as a Level I Trauma Center, a hospital shall have the following:

(1) A trauma program and a trauma service that have been operational for at least ~~six~~ 12 months prior to application for designation;

(2) Membership in and inclusion of all trauma patient records in the North Carolina Trauma Registry for at least ~~six~~ 12 months prior to submitting a Request for Proposal;

(3) ~~Trauma~~ A trauma medical director who is a board-certified general surgeon. The trauma medical director must:

(a) Have a minimum of three years clinical experience on a trauma service or trauma fellowship training;

(b) Serve on the center's trauma service;

(c) Participate in providing care to patients with life-threatening or urgent injuries;

(d) Participate in the North Carolina Chapter of the ACS Committee on Trauma as well as other regional and national trauma organizations;

(e) Remain a current provider in the ACS' ~~Advanced Trauma Life Support~~ ATLS Course and in the provision of trauma-related instruction to other health care personnel; and

(f) Be involved with trauma research and the publication of results and presentations.

(4) A full-time ~~trauma nurse coordinator (TNC)/program manager (TPM)~~ TNC/TPM who is a registered nurse, licensed by the North Carolina Board of Nursing;

(5) A full-time ~~trauma registrar (TR)~~ TR who has a working knowledge of medical terminology, is able to operate a personal computer, and has ~~demonstrated~~ the ability to extract data from the medical record;

(6) A hospital department/division/section for general surgery, neurological surgery, emergency medicine, anesthesiology, and orthopaedic surgery, with designated chair or physician liaison to the trauma program for each;

(7) Clinical capabilities in general surgery with ~~two~~ separate posted call schedules. One shall be for trauma, one for general ~~surgery.~~ surgery and a back-up call schedule for trauma. In those instances where a physician may simultaneously be listed on both schedules, there must be a defined back-up surgeon listed on the schedule to allow the trauma surgeon to provide care for the trauma patient. ~~The trauma service director shall specify, in writing, the specific credentials that each back-up surgeon must have. These must state that the back-up surgeon has surgical privileges at the trauma center and is boarded or eligible in general surgery (with board certification in general surgery within five years of completing residency).~~ If a trauma surgeon is simultaneously on call at more than one hospital, there shall be a defined, posted trauma surgery back-up call schedule composed of surgeons credentialed to serve on the trauma panel.

(8) ~~Response of a~~ A trauma team to provide evaluation and treatment of a trauma patient 24 hours per day that includes:

(a) An in-house ~~Post Graduate Year 4 (PGY4)~~ trauma attending or PGY4 or senior general surgical ~~resident, at a minimum, who is a member of that hospital's surgical residency program and responds within 20 minutes of notification;~~ resident. The trauma attending participates in therapeutic decisions and is present at all operative procedures.

~~(b) A trauma attending whose presence at the patient's bedside within 20 minutes of notification is documented and who participates in therapeutic decisions and is present at all operative procedures;~~

~~(c)~~ (b) An emergency physician who is present in the Emergency Department 24 hours per day who is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine). Emergency physicians caring only for pediatric patients may, as an alternative, be boarded or prepared in pediatric emergency medicine. Emergency physicians must be board-certified within five years after successful completion of a residency in emergency medicine and serve as a designated member of the trauma team to ensure immediate care for the injured patient until the arrival of the trauma surgeon;

~~(d)~~ (c) Neurosurgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the trauma team leader, unless there is either an in-house attending neurosurgeon, a ~~Post Graduate Year 2 (PGY2)~~ PGY2 or higher in-house neurosurgery resident or an in-house trauma surgeon or emergency physician as long as the institution can document management guidelines and annual continuing medical education for neurosurgical emergencies. There must be a specified ~~written~~ back-up on the call schedule whenever the neurosurgeon is simultaneously on-call at a hospital other than the trauma center;

~~(e)~~ (d) Orthopaedic surgery specialists who are never simultaneously on-call at another Level II or higher trauma center, who are promptly available, if requested by the trauma team leader, unless there is either an in-house attending orthopaedic surgeon, a ~~Post Graduate Year 2 (PGY2)~~ PGY2 or higher in-house orthopaedic surgery resident or an in-house trauma surgeon or emergency physician as long as the institution can document management guidelines and annual continuing medical education for orthopaedic emergencies. There must be a specified ~~written~~ documented back-up on the call schedule whenever the orthopaedist is simultaneously on-call at a hospital other than the trauma center;

~~(f)~~ (e) An in-house anesthesiologist or a ~~Clinical Anesthesiology Year 3 (CA3)~~ CA3 resident as long as an anesthesiologist on-call is advised and promptly available if requested by the trauma team leader, and

~~(g)~~ (f) Registered nursing personnel trained in the care of trauma patients.

(9) A written credentialing process established by the Department of Surgery to approve mid-level practitioners and attending general surgeons covering the trauma service. The surgeons must have board certification in general surgery within five years of completing residency;

(10) Neurosurgeons and orthopaedists serving the trauma service who are currently board certified or eligible. Those who are eligible must be board certified within five years after successful completion of the residency;

(11) ~~Standard written~~ Written protocols relating to trauma management formulated and ~~routinely updated;~~ updated to remain current;

(12) Criteria to ensure team activation prior to ~~arrival~~ arrival, and trauma attending arrival within 15 minutes of the arrival of ~~trauma/burn~~ trauma and burn patients ~~to~~ that include the ~~following:~~ following conditions:

(a) Shock;

(b) Respiratory distress;

(c) Airway compromise;

(d) Unresponsiveness ~~(Glasgow Coma Scale~~ (GSC less than ~~8)~~ eight) with potential for multiple injuries; ~~and~~

(e) Gunshot wound to head, neck, or ~~torso.~~ torso;

(f) Patients receiving blood to maintain vital signs; and

(g) ED physician's decision to activate.

(13) Surgical evaluation, based upon the following criteria, by the ~~health professional who is promptly available:~~ trauma attending surgeon who is promptly available:

(a) Proximal amputations;

(b) Burns meeting institutional transfer criteria;

(c) Vascular compromise;

(d) Crush to chest or pelvis;

(e) Two or more proximal long bone fractures; and

(f) Spinal cord injury.

A senior surgical resident may initiate the evaluation.

(14) Surgical consults, at the request of the ED physician based upon the following criteria, by the ~~health professional who is promptly available:~~ trauma attending surgeon who is promptly available:

(a) Falls greater than 20 feet;

(b) Pedestrian struck by motor vehicle;

(c) Motor vehicle crash with:

(i) Ejection (includes motorcycle);

(ii) Rollover;

(iii) Speed greater than 40 mph; or

(iv) Death of another individual ~~at the scene;~~ in the same vehicle;

(d) Extremes of age, less than five or greater than 70 ~~years;~~ years.

A senior surgical resident may initiate the evaluation.

(15) Clinical capabilities (promptly available if requested by the trauma team leader, with a posted on-call schedule), ~~to~~ that include individuals credentialed in the following:

(a) Cardiac surgery;

(b) Critical care;

(c) Hand surgery;

(d) Microvascular/replant ~~surgery;~~ surgery, or if service is not available, a transfer agreement must exist;

(e) Neurosurgery (The neurosurgeon must be dedicated to one hospital or a back-up call schedule must be available. If fewer than 25 emergency neurosurgical trauma operations are done in a year, and the neurosurgeon is dedicated only to that hospital, then a published back-up call list is not necessary.)

(f) Obstetrics/gynecologic surgery;

(g) Opthalmic surgery;

(h) ~~Oral/maxillofacial surgery;~~ Oral maxillofacial surgery (may be fulfilled by a combination of ENT, Plastic, or OMF specialties);

(i) Orthopaedics (dedicated to one hospital or a back-up call schedule must be available);

(j) Pediatric surgery;

(k) Plastic surgery;

(l) Radiology;

(m) Thoracic surgery; and

(n) Urologic surgery.

(16) An Emergency Department that has:

(a) A designated physician director who is board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine);

(b) 24-hour-per-day staffing by physicians physically present in the ~~Emergency Department~~ ED such that:

(i) At least one physician on every shift in the ~~Emergency Department~~ ED is either board-certified or prepared in emergency medicine (by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine) to serve as the designated member of the trauma team ~~at least~~ to ensure immediate care until the arrival of the trauma surgeon. Emergency physicians caring only for pediatric patients may, as an alternative, be boarded

in pediatric emergency medicine. All emergency physicians must be board-certified within five years after successful completion of the residency;

(ii) All remaining emergency physicians, if not board-certified or prepared in emergency medicine as outlined in ~~Item~~ Subitem (16)(b)(i) of this Rule, are board-certified, or eligible by the American Board of Surgery, American Board of Family Practice, or American Board of Internal Medicine, with each being board-certified within five years after successful completion of a residency; and

(iii) All emergency physicians practice emergency medicine as their primary specialty.

(c) Nursing personnel with experience in trauma care who continually monitor the trauma patient from hospital arrival to disposition to an intensive care unit, operating room, or patient care unit;

(d) Equipment for patients of all ages to include:

(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, pocket masks, and oxygen);

(ii) Pulse oximetry;

(iii) End-tidal carbon dioxide determination equipment;

(iv) Suction devices;

(v) Electrocardiograph-oscilloscope-defibrillator with internal paddles;

(vi) Apparatus to establish central venous pressure monitoring;

(vii) Intravenous fluids and administration devices ~~to~~ that include large bore catheters and intraosseous infusion devices;

(viii) Sterile surgical sets for airway control/cricothyrotomy, thoracotomy, vascular access, thoracostomy, peritoneal lavage, and central line insertion;

(ix) Apparatus for gastric decompression;

(x) 24-hour-per-day x-ray capability;

(xi) Two-way communication equipment for communication with the emergency transport system;

(xii) Skeletal traction devices, including capability for cervical traction;

(xiii) Arterial catheters;

(xiv) Thermal control equipment for patients;

(xv) Thermal control equipment for blood and fluids;

(xvi) ~~Rapid~~ A rapid infuser system;

(xvii) ~~Broselow tape;~~ A dosing reference and measurement system to ensure appropriate age related medical care;

(xviii) Sonography; and

(xix) ~~Doppler.~~ A doppler.

(17) An operating suite that is immediately available 24 hours per day and has:

(a) 24-hour-per-day immediate availability of in-house staffing;

(b) Equipment for patients of all ages ~~to include:~~ that includes:

(i) Cardiopulmonary bypass capability;

~~(ii) Operating microscope;~~

~~(iii)~~ (ii) Thermal control equipment for patients

~~(iv)~~ (iii) Thermal control equipment for blood and fluids;

~~(v)~~ (iv) 24-hour-per-day x-ray capability including c-arm image intensifier;

~~(vi)~~ (v) Endoscopes and bronchoscopes;

~~(vii)~~ (vi) Craniotomy instruments;

~~(viii)~~ (vii) ~~Capability~~ The capability of fixation of long-bone and pelvic fractures; and

~~(ix)~~ (viii) ~~Rapid~~ A rapid infuser system.

(18) A postanesthetic recovery room or surgical intensive care unit that has:

(a) 24-hour-per-day in-house staffing by registered nurses;

(b) Equipment for patients of all ages ~~to include:~~ that includes:

(i) ~~Capability~~ The capability for resuscitation and continuous monitoring of temperature, hemodynamics, and gas exchange;

(ii) ~~Capability~~ The capability for continuous monitoring of intracranial pressure;

(iii) Pulse oximetry;

(iv) End-tidal carbon dioxide determination capability;

(v) Thermal control equipment for patients; and

(vi) Thermal control equipment for blood and fluids.

(19) An intensive care unit for trauma patients that has:

(a) A designated surgical director for trauma patients;

(b) A physician on duty in the intensive care unit 24 hours per day or immediately available from within the hospital as long as this physician is not the sole physician on-call for the Emergency Department;

(c) Ratio of one nurse per two patients on each shift;

(d) Equipment for patients of all ages ~~to include:~~ that includes:

(i) Airway control and ventilation equipment (laryngoscopes, endotracheal tubes, bag-mask resuscitators, and pocket masks);

(ii) ~~Oxygen~~ An oxygen source with concentration controls;

(iii) ~~Cardiac~~ A cardiac emergency cart;

(iv) ~~Temporary,~~ A temporary transvenous pacemaker;

(v) ~~Electrocardiograph-oscilloscope-defibrillator~~ An electrocardiograph-oscilloscope-defibrillator with internal paddles;

(vi) Cardiac output monitoring capability;

(vii) Electronic pressure monitoring capability;

(viii) ~~Mechanical~~ A mechanical ventilator;

(ix) Patient weighing devices;

(x) Pulmonary function measuring devices;

(xi) Temperature control devices; and

(xii) Intracranial pressure monitoring devices.

(e) Within 30 minutes of request, the ability to perform blood gas measurements, hematocrit level, and chest x-ray studies;

(20) Acute hemodialysis capability;

(21) Physician-directed burn center staffed by nursing personnel trained in burn care or a ~~written~~ transfer agreement with a burn center;

(22) Acute spinal cord management capability or ~~written~~ transfer agreement with a hospital capable of caring for a spinal cord injured patient;

(23) Radiological capabilities that include:

(a) 24-hour-per-day in-house radiology technologist;

(b) 24-hour-per-day in-house computerized tomography technologist;

(c) Sonography;

(d) Computed tomography;

(e) Angiography;

(f) Magnetic resonance imaging; and

(g) Resuscitation equipment ~~to include: airway~~ that includes airway management and IV therapy.

(24) Respiratory therapy services available in-house 24 hours per day;

(25) 24-hour-per-day clinical laboratory service that must include:

(a) ~~Standard analysis~~ Analysis of blood, urine, and other body fluids, including micro-sampling when appropriate;

(b) Blood-typing and cross-matching;

(c) Coagulation studies;

(d) Comprehensive blood bank or access to community central blood bank with storage facilities;

(e) Blood gases and pH determination; and

(f) Microbiology.

(26) A rehabilitation service that provides:

(a) A staff trained in rehabilitation care of critically injured patients;

(b) ~~For major trauma patients, functional~~ Functional assessment and recommendations regarding short- and long-term rehabilitation needs within one week of the patient's admission to the hospital or as soon as hemodynamically stable;

(c) ~~Full in-house~~ In-house rehabilitation service or a ~~written~~ transfer agreement with a rehabilitation facility accredited by the Commission on Accreditation of Rehabilitation Facilities;

(d) Physical, occupational, speech therapies, and social services; and

(e) Substance abuse evaluation and counseling capability.

(27) A performance improvement program, as outlined in the North Carolina Chapter of the American College of Surgeons Committee on Trauma document "Performance Improvement Guidelines for North Carolina Trauma Centers," incorporated by reference in accordance with G.S. 150B-21.6, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost. This performance improvement program must include:

(a) The ~~trauma registry~~ state Trauma Registry ~~agreed to by the North Carolina State Trauma Advisory Committee and OEMS,~~ whose data is submitted to the OEMS at least ~~quarterly~~ weekly and includes all the center's trauma patients as defined in Rule ~~.0801(33)~~ .0102(57) of this Subchapter who are either diverted to an affiliated hospital, admitted to the trauma center for greater than ~~23:59 hours (24 hours or more)~~ 24 hours from an ED or hospital, die in the ED, are DOA or are transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital);

(b) Morbidity and mortality reviews ~~to include~~ including all trauma deaths;

(c) Trauma performance committee that meets at least ~~quarterly, to include~~ quarterly and includes physicians, nurses, pre-hospital personnel, and a variety of other healthcare providers, and reviews policies, procedures, and system issues and whose members or designee attends at least ~~50%~~ 50 percent of the regular meetings;

(d) Multidisciplinary peer review committee that meets at least quarterly and includes physicians from trauma, neurosurgery, orthopaedics, emergency medicine, anesthesiology, and other specialty physicians, as needed, specific to the case, and the trauma nurse coordinator/program manager and whose members or designee attends at least ~~50%~~ 50 percent of the regular meetings;

(e) Identification of discretionary and non-discretionary audit filters;

(f) Documentation and review of times and reasons for trauma-related diversion of patients from the scene or referring hospital;

(g) Documentation and review of response times for trauma surgeons, neurosurgeons, anesthesiologists or airway managers, and orthopaedists. All must demonstrate ~~80%~~ 80 percent compliance.

(h) Monitoring of trauma team notification times;

(i) Review of pre-hospital trauma care ~~to include~~ that includes dead-on-arrivals; and

(j) Review of times and reasons for transfer of injured patients.

(28) An outreach program ~~to include:~~ that includes:

(a) ~~Written transfer~~ Transfer agreements to address the transfer and receipt of trauma patients;

(b) Programs for physicians within the community and within the referral area (~~to~~ that include telephone and on-site consultations) about how to access the trauma center resources and refer patients within the system;

(c) Development of a Regional Advisory Committee ~~(RAC)~~ as specified in Rule .1102 of this Subchapter;

(d) Development of regional criteria for coordination of trauma care;

(e) Assessment of trauma system operations at the regional level; and

(f) ATLS.

(29) A program of injury prevention and public education ~~to include:~~ that includes:

(a) Epidemiology research ~~to include~~ that includes studies in injury control, collaboration with other institutions on research, monitoring progress of prevention programs, and consultation with qualified researchers on evaluation measures;

(b) Surveillance methods ~~to include~~ that includes trauma registry data, special Emergency Department and field collection projects;

(c) Designation of a injury prevention coordinator; and

(d) Outreach activities, program development, information resources, and collaboration with existing national, regional, and state trauma programs.

(30) A trauma research program designed to produce new knowledge applicable to the care of injured patients ~~to include:~~ that includes:

(a) ~~Identifiable~~ An identifiable institutional review board process;

(b) Extramural educational presentations that must include 12 education/outreach presentations over a three-year period; and

(c) 10 peer-reviewed publications over a three-year period that could come from any aspect of the trauma program.

(31) A documented continuing education program for staff physicians, nurses, allied health personnel, and community physicians ~~to include:~~ that includes:

(a) A general surgery residency program;

(b) 20 hours of Category I or II trauma-related continuing medical education (as approved by the Accreditation Council for Continuing Medical Education) every two years for all attending general surgeons on the trauma service, orthopaedists, and neurosurgeons, with at least ~~50%~~ 50 percent of this being extramural;

(c) 20 hours of Category I or II trauma-related continuing medical education (as approved by the Accreditation Council for Continuing Medical Education) every two years for all emergency physicians, with at least ~~50%~~ 50 percent of this being extramural;

(d) ~~Advanced Trauma Life Support (ATLS)~~ ATLS completion for general surgeons on the trauma service and emergency physicians. Emergency physicians, if not boarded in emergency medicine, must be current in ATLS;

(e) 20 contact hours of trauma-related continuing education (beyond in-house in-services) every two years for the ~~trauma nurse coordinator/program manager;~~ TNC/TPM;

(f) 16 hours of trauma-registry-related or trauma-related continuing education every two years, as deemed appropriate by the trauma nurse coordinator/program manager for the trauma registrar;

(g) At least an ~~80%~~ 80 percent compliance rate for 16 hours of trauma-related continuing education (as approved by the ~~trauma nurse coordinator/program manager)~~ TNC/TPM) every two years related to trauma care for RN's and LPN's in transport programs, Emergency Departments, primary intensive care units, primary trauma floors, and other areas deemed appropriate by the ~~trauma nurse coordinator/program manager;~~ TNC/TPM; and

(h) 16 hours of trauma-related continuing education every two years for mid-level practitioners routinely caring for trauma patients.

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004.